

SAT Report
PMN Number: **L-13-0176**
SAT Date: **3/1/2013**
Print Date: **8/19/2014**

Related cases:

[REDACTED]

Concern levels:

Type of Concern:	<u>Health</u>	<u>Eco</u>	<u>Comments</u>
Level of Concern:	1-2	1	

<u>Persistence</u>	<u>Bioaccum</u>	<u>Toxicity</u>	<u>Comments</u>
3	3	1	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	

Exposure Based Review:

Health: No
Ecotox: No

Routes of exposure:

Health: Dermal Inhalation
Ecotox: No releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: L-13-0176

FATE:

Liquid with MP = -43 C (M)
 log Kow = 5.92 (E)
 S = 0.02 mg/L at 25 C (E)
 VP = 12.8 torr at 25 C (M)
 BP = 130 C (M)
 H = 2.98E+5 (E)
 log Koc = 6.46 (E)
 log Fish BCF = 3.57 (E)
 log Fish BAF = 5.33 (E)
 POTW removal (%) = 90-99 via sorption and stripping
 Time for complete ultimate aerobic biodeg > mo
 Sorption to soils/sediments = v.strong
 Volatilization half-life from a standard river = 2 hrs
 Volatilization half-life from a standard lake = 8 da
 PBT Potential: P3B3
 *CEB FATE: Migration to ground water = negl

Health:

Health Summary: Absorption is poor all routes based on physical/chemical properties. The Standard Review for [REDACTED] (perfluorodimethylcyclohexane derivatives) supported a concern for neurotoxicity at high exposure levels. The Standard Review did not support concern for liver effects based on the lack of liver toxicity in the acute study submitted for [REDACTED]; cardiac sensitization based on evidence in the literature that increasing the degree of fluorination of a chemical decreases the cardiac sensitization potential; developmental/reproductive toxicity because there were no close analogs that have been shown to cause developmental or reproductive toxicity. New information since the Standard Review for [REDACTED] shows that octafluoropropane is positive for cardiac sensitization in 1 of 6 dogs at 40% concentration in the air with no response at 30% concentration or less [REDACTED]. This is not considered to be a close analog because it is much smaller than the LVE compound. The nonreactivity and chemical stability of perfluorocarbons lead to a concern about high global warming potential and long atmospheric lifetimes. Low moderate concern.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	96-h	LC50	*		
daphnid	48-h	LC50	*		
green algal	96-h	EC50	*		
fish	—	chronic value	*		
daphnid	—	chronic value	*		
algal	—	chronic value	*		
Sewage Sludge	3-h	EC50	—		

Sewage Sludge	–	Chronic Value	–		
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Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)		*
SARs	Neutral Organics	
SAR Class	Perfluoro Alkane	
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: L Keifer 564-8916

Focus Report
New Chemicals Program
PMN Number: **L-13-0176**

Focus Date: 03/11/2013 12:00:00 AM Report Status: Completed
Consolidated Set:
Focus Chair: Kristan Markey Contractor: Bryan Amagai

I. Notice Information

Submitter: Johnson Matthey Inc. CAS Number: 423-02-9
Chemical Name: Cyclohexane, 1,1,2,2,3,3,4,4,5,5,6-undecafluoro-6-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]-
Use: Tracer chemical to measure flow in deep oil-bearing strata or hydrocarbon leak measurements.
Similar materials submitted concurrently: [REDACTED] P2 Claim: The LVE material is intended to replace radionuclide tracers.

Other Uses:

PV-Max: 1,000 Kg/yr Binding Option: Yes
Manufacture: Import: X

II. SAT Results

(1) Health Rating: 1-2 Eco Rating: 1 Comments: ;

Occupational: 2-3A Non-Occupational: 2 Environmental: 2

(1) PBT: 3 3 1 Comments:

III. OTHER FACTORS

Categories:

Health Chemical Category: Ecotox Category: Neutral Organics

Related Cases/Regulatory History:

Health related Cases:

Ecotox Related Cases:

Regulatory History:

(Same As L-13-0170-0173) - GRANTED WITH CONDITION

(Same As L-13-0176) - GRANTED WITH CONDITION

- GRANTED WITH CONDITION

8 - GRANTED WITH LETTER

3 - GRANTED

- GRANTED WITH CONDITION

- WITHDRAWN - OTHER

- WITHDRAWN/FACE 5E

[REDACTED] - GRANTED WITH CONDITION

- GRANTED

- GRANTED WITH CONDITION

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: None listed.

Respirator: None listed.

Health Effects: Not classified.

TLV/PEL (PMN or raw material): - None established.

LVEPPE: Fume Hood with adequate air face velocity of 100 feet per minute, Impervious Gloves, Tyvek Suit, Goggles

Exposure Based Information:

Exposure Based Review: N
Exposure Based Review (Eco): N
Exposure Based Review
(Non Occupational):

Exposure Based Review (Health): N
Exposure Based (Occupational): No
Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

L-13-0176
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Health Summary:

Absorption is poor all routes based on physical/chemical properties. The Standard Review for [REDACTED] supported a concern for neurotoxicity at high exposure levels. The Standard Review did not support concern for liver effects based on the lack of liver toxicity in the acute study submitted for [REDACTED]; cardiac sensitization based on evidence in the literature that increasing the degree of fluorination of a chemical decreases the cardiac sensitization potential; developmental/reproductive toxicity because there were no close analogs that have been shown to cause developmental or reproductive toxicity. New information since the Standard Review for [REDACTED] shows that octafluoropropane is positive for cardiac sensitization in 1 of 6 dogs at 40% concentration in the air with no response at 30% concentration or less [REDACTED]. This is not considered to be a close analog because it is much smaller than the LVE compound. The nonreactivity and chemical stability of perfluorocarbons lead to a concern about high global warming potential and long atmospheric lifetimes. Low moderate concern.

Ecotox:

Ecotox Values:

Fish 96-h LC50: *(P)
Daphnid 48-h LC50: *(P)
Green algal 96-h EC50: *(P)
Fish Chronic Value: *(P)
Daphnid ChV: *(P)
Algal ChV: *(P)

Ecotox values comments:

Predictions are based on SARs for neutral organic chemicals; SAR chemical class = perfluorocyclicC6-iso C3; MW 450; log Kow = 5.26 (EPI), 6.80 (ACD); S < 0.001 mg/L at 25 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <180.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotox Factors:

Assessment Factor: 10
Concern Concentration:

V. Summary of Exposures/Releases

Engineering Summary: L-13-0176

Exposures/Releases	Release	Release	Release
Scenario	Processing: Repackaging/Formulation	Processing: Repackaging/Formulation	Processing: Repackaging/Formulation
Sites	1	1	1
Media	Air	Water or Incineration or Landfill	Air
Descriptor A	Typical	High End	Output 2
Quantity A (kg/site/day)	1.4E-2	3.0E-1	1.3E-1
Frequency A (day/year)	20	20	20
Descriptor B	Worst Case		
Quantity B (kg/site/day)	1.4E-2		
Frequency B (day/year)	20		
From	Unloading Liquid Raw Material from Containers	Cleaning Liquid Residuals from Containers Used to Transport the Raw Material	Cleaning Liquid Residuals from Containers Used to Transport the Raw Material
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	Processing: Repackaging/Formulation	Processing: Repackaging/Formulation	Use: Injection of Tracer Chemical into Oil-Bearing Strata
Sites	1	1	1
Media	Water or Incineration or Landfill	Air	Water or Incineration or Landfill
Descriptor A	Conservative	Typical	High End
Quantity A (kg/site/day)	5.0E-1	1.7E-2	1.2E-1
Frequency A (day/year)	20	20	50
Descriptor B		Worst Case	
Quantity B (kg/site/day)		3.4E-2	
Frequency B (day/year)		20	
From	Equipment Cleaning Losses of Liquids from a Single, Small Vessel	Loading Liquid Product into 5 L Containers	Cleaning Liquid Residuals from Containers Used to Transport the Raw Material
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: L-13-0176

Exposures/Releases	Release	Release	Exposure
Scenario	Use: Injection of Tracer Chemical into Oil-Bearing Strata	Use: Injection of Tracer Chemical into Oil-Bearing Strata	Processing: Repackaging/Formulation
Sites	1	1	1
Media	Air	Incineration	Dermal
Descriptor A	Typical	Output 2	High End
Quantity A (kg/site/day)	5.3E-3	2.0E+1	1.7E+3
Frequency A (day/year)	50	50	20
Descriptor B	Worst Case		
Quantity B (kg/site/day)	5.3E-3		
Frequency B (day/year)	50		
From	Unloading Liquid Raw Material from Containers	Oil Production	Unloading Liquid Raw Material from Containers
Workers			3
Exposure Type			Liquid

Engineering Summary: Exposures/Releases	Exposure	Exposure	Exposure
Scenario	Processing: Repackaging/Formulation	Processing: Repackaging/Formulation	Processing: Repackaging/Formulation
Sites	1	1	1
Media	Inhalation	Dermal	Inhalation
Descriptor A	Worst Case	High End	Worst Case
Quantity A (kg/site/day)	2.0E+2	7.1E+2	4.9E+2
Frequency A (day/year)	20	20	20
Descriptor B	Typical		Typical
Quantity B (kg/site/day)	6.5E+0		8.1E+0
Frequency B (day/year)	20		20
From	Unloading Liquid Raw Material from Containers	Loading Liquid Product into 5 L Containers	Loading Liquid Product into 5 L Containers
Workers	3	3	3
Exposure Type	Vapor	Liquid	Vapor

V. Summary of Exposures/Releases

Engineering Summary: L-13-0176

Exposures/Releases	Exposure	Exposure	
Scenario	Use: Injection of Tracer Chemical into Oil-Bearing Strata	Use: Injection of Tracer Chemical into Oil-Bearing Strata	
Sites	1	1	
Media	Dermal	Inhalation	
Descriptor A	High End	Worst Case	
Quantity A (kg/site/day)	7.1E+2	7.7E+1	
Frequency A (day/year)	50	50	
Descriptor B		Typical	
Quantity B (kg/site/day)		2.6E+0	
Frequency B (day/year)		50	
From	Unloading Liquid Raw Material from Containers	Unloading Liquid Raw Material from Containers	
Workers			
Exposure Type	Liquid	Vapor	

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: LVE Final Conditional Grant

Decision Date: 03/11/2013

Type of Decision:

Rationale:

L-13-0176 was given a final conditional grant based on binding to the production volume and the uses described in the PMN. Absorption is poor all routes based on physical/chemical properties. Human health hazard concerns were low-moderate based on cardiac sensitization. Workers are expected to be exposed via inhalation and dermal routes. Potential risks to workers were mitigated by appropriate PPE. Ecotoxicity hazard concerns were low based on EcoSAR predictions for neutral organics. Potential risks to the environment were low based on no effects expected at saturation. The submitter bound this LVE to 1,000 kg/yr, and EPA assessed it at this volume..

COC: No effects at saturation

Summary of Exposures and Releases

Proc

1 site, 20 days/year, 3 workers

Inhalation (Vapor): Typical: 6.5E+0 mg/day, Worst Case: 2.0E+2 mg/day

Inhalation (Vapor): Typical: 8.1E+0 mg/day, Worst Case: 4.9E+2 mg/day

Dermal: 1.7E+3 mg/day (98% Liquid)

Dermal: 7.1E+2 mg/day (40% Liquid)

Releases to Water: 3.0E-1 kg/site-day over 20 days/yr

Or Incineration or Landfill

Releases to Water: 5.0E-1 kg/site-day over 20 days/yr

Or Incineration or Landfill

Releases to Air: Typical: 1.4E-2 kg/site-day over 20 days/yr, Worst Case:

1.4E-2 kg/site-day over 20 days/yr

Releases to Air: 1.3E-1 kg/site-day over 20 days/yr

Releases to Air: Typical: 1.7E-2 kg/site-day over 20 days/yr, Worst Case:

3.4E-2 kg/site-day over 20 days/yr

Fate Releases to Air:

Stack Air: LADD: 4.34E-06 mg/kg/day ADR: 9.91E-04 mg/kg/day

Fugitive Air: LADD: 7.87E-06 mg/kg/day ADR: 4.47E-03 mg/kg/day

Fate Releases to Water (Removal Rate 90%):

SWC: 10.31 ppb

DW: LADD: 8.63E-07 mg/kg/day; ADR: 5.03E-04 mg/kg/day

FI: LADD: 1.39E-05 mg/kg/day, ADR: 1.36E-02 g/kg/day

Use

1 site, 50 days/year, 3 workers

Inhalation (Vapor): Typical: 2.6E+0 mg/day, Worst Case: 7.7E+1 mg/day

Dermal: 7.1E+2 mg/day (40% Liquid)

Releases to Water: 1.2E-1 kg/site-day over 50 days/yr

Or Incineration or Landfill

Releases to Air: Typical: 5.3E-3 kg/site-day over 50 days/yr, Worst Case:

5.3E-3 kg/site-day over 50 days/yr

Releases via Incineration: 2.0E+1 kg/site-day over 50 days/yr

Fate Releases to Air:

Stack Air: LADD: 2.73E-04 mg/kg/day ADR: 2.57E-02 mg/kg/day

Fugitive Air: LADD: 5.84E-07 mg/kg/day ADR: 1.33E-04 mg/kg/day

Fate Releases to Water (Removal Rate 90%):

SWC: 11.32 ppb

DW: LADD: 1.15E-06 mg/kg/day; ADR: 5.17E-04 mg/kg/day

FI: LADD: 1.85E-05 mg/kg/day, ADR: 7.28E-03 mg/kg/day

P2 Rec Comments:

Testing:

Final Recommended:

Health:

Eco:

Fate:

Other: